FDA U.S. FOOD & DRUG ADMINISTRATION

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Production and Service Controls Process: Part 2

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Course Prerequisites

- Successful completion of the following MDSAP training module is a prerequisite to this course:
  - Introduction to the MDSAP Program
  - Overview of the MDSAP Audit Process
  - MDSAP: Management Process
  - MDSAP: Measurement, Analysis and Improvement Process
  - MDSAP: Design and Development Process
  - MDSAP: Production and Service Controls Process: Part 1

Learning Objectives

- Review the purpose of auditing the Production and Service Controls process
- Explain the audit tasks for Production and Service Controls process, **Part 2** to include:
  - Description and related Clauses and Regulations
  - Country-specific requirements and assessment of conformity
  - Links to other MDSAP processes

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Purpose of Auditing

- The Production and Service Controls process is audited to:
  - Verify that the manufacturer's processes are capable of ensuring that products will meet specifications
    - Includes testing, infrastructure, facilities, equipment, and servicing

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Tasks 1-10

- Audit tasks 1-10 were discussed in MDSAP training module Production and Service Controls Process, Part 1

- Part 2 will commence with audit task 11

Task 11

11. **Verify that the processes used in production and service are appropriately controlled, monitored, operated within specified limits and documented in the product realization records. *In addition, verify that risk control measures identified by the manufacturer for production processes are implemented, monitored and evaluated*.**

    Clause and Regulation: [ISO 13485:2016: 7.1, 7.5.1, 8.1, 8.2.5; TG(MD)R Sch1 P1 2, Sch3 P1 1.4(5)(b)&(e); RDC ANVISA 16/2013: 2.4, 5.1.1, 5.1.6, 8.2, 9.1; MHLW MO169: 26, 40, 54, 57; 21 CFR 820.70(a), 820.75(b), 820.250]

MDSAP Audit Approach

Task 11

- Additional country-specific requirements: Australia (TGA)

- Assessing conformity:
  - Confirm that procedures available to production personnel are the most current approved revisions
  - Compare work instructions with what is actually being done
  - Compare product acceptance criteria with acceptance activity results
  - Review control charts against specified requirements

Detailed information on how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 6: Production and Service Controls, under Task 11

Task 11

- *Links:*
  - *Design and Development*
    - The design outputs for a device include documents such as diagrams, drawings, specifications, procedures, and the production processes that are essential to the proper manufacturing of the device

Task 12

12. Verify that personnel are competent to implement and maintain the processes in accordance with the requirements identified by the organization.

Clause and Regulation: [ISO 13485:2016: 6.2; RDC ANVISA 16/2013: 2.3.2; MHLW MO169: 22; 21 CFR 820.25, 820.70(d), 820.75(b)]

MDSAP Audit Approach

Task 12

- Additional country-specific requirements: None

- Assessing conformity:

  Detailed information on how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 6: Production and Service Controls, under Task 12

Task 12

- *Links:*
  - *Management*
    - When appropriate, review the training records for those employees whose activities have contributed to process nonconformities

Task 13

13. Confirm the organization has determined the monitoring and measuring devices needed to provide evidence of conformity to specified requirements. Verify that the monitoring and measuring equipment used in production and service has been identified, adjusted, calibrated and maintained, and capable of producing valid results.

Clause and Regulation: [ISO 13485:2016: 7.5.1, 7.6; TG(MD)R Sch3 P1 1.4(5)(e); RDC ANVISA 16/2013: 5.1.5,5.4; MHLW MO169: 40, 53; 21 CFR 820.70(g), 820.72]

MDSAP Audit Approach

Task 13

- Additional country-specific requirements: None

- Assessing conformity:
  - Confirm that the production and test equipment is suitable for its intended purpose and capable of giving valid results
  - Review maintenance, control, and calibration procedures for the equipment selected for review
  - Verify that the organization made an assessment of the effect of the out-of-tolerance situation on in-process, finished, or released devices, based on risk

Detailed information on how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 6: Production and Service Controls, under Task 13

Task 14

14. Confirm the organization assesses (and records) the validity of previous measurements when equipment is found not to conform to specified requirements, and takes appropriate action on the equipment and any product affected. Verify that the control of the monitoring and measuring devices is adequate to ensure valid results. Confirm that monitoring and measuring devices are protected from damage or deterioration.

Clause and Regulation: [ISO 13485:2016: 7.6; TG(MD)R Sch3 P1 1.4(5)(e); RDC ANVISA 16/2013: 5.4; MHLW MO169: 53; 21 CFR 820.72(a)]

MDSAP Audit Approach

Task 14

- Additional country-specific requirements: None

- Assessing conformity:
  - Confirm that the organization has the proper procedures and controls in place to preserve the proper functioning of monitoring, measuring, and test equipment

Detailed information on how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 6: Production and Service Controls, under Task 14

Task 15

15. **If the selected process is software controlled or if software is used in production equipment or the quality management system, verify that the software is validated for its intended use. Software validation may be part of equipment qualification.**

    Clause and Regulation: [ISO 13485:2016: 4.1.6, 7.5.6, 7.6; RDC ANVISA 16/2013: 5.5.2; MHLW MO169: 5-6, 45, 53 (Old: 45, 53); 21 CFR 820.70(i)]

MDSAP Audit Approach

Task 15

- Additional country-specific requirements: None

- Assessing conformity:
  - Review the software validation documents and records
  - Assess the systems most likely to have an impact on the finished device's ability to meet specified requirements

  Detailed information on how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 6: Production and Service Controls, under task 15

Task 16

16. **Determine if the medical device organization has established and maintained a file for each type of device that includes or refers to the location of device specifications, production process specifications, quality assurance procedures, traceability requirements, packaging and labeling specifications, and when applicable requirements for installation and servicing. .** ***Confirm that the manufacturer determined the extent of traceability based on the risk posed by the device in the event the device does not meet specified requirements.***

Clause and Regulation: [ISO 13485:2016: 4.2.1, 4.2.3, 7.1, 7.5.8, 7.5.9.1; TG(MD)R Sch3 P1 1.4(5) (c),(d),(e) & 1.9; RDC ANVISA 16/2013: 1.2.26, 2.4, 4.2, 5.2, 6.4; CMDR 9(2), 21-23, 52-56, 66-68; MHLW MO169: 6,7-2, 26, 47, 48 (Old: 6, 26, 47, 48); 21 CFR 820.65, 820.181]

MDSAP Audit Approach

Task 16

- Additional country-specific requirements: Australia (TGA), Brazil (ANVISA), Canada (HC), United States (FDA)

- Assessing conformity:
  - Confirm that the required records have been established

Detailed information on how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 6: Production and Service Controls, under Task 16

Task 16

- *Links:*
  - *Design and Development*
    - During audit of the Design and Development process:
      - Confirm that the essential design outputs for the proper functioning of the device have been identified

Task 17

17. **Determine if the medical device organization has established and maintained a record of the amount manufactured and approved for distribution for each batch of medical devices, the record is verified and approved, the device is manufactured according to the file referenced in Task 16, and the requirements for product release were met and documented.**

Clause and Regulation: [ISO 13485:2016: 4.2.1, 7.5.1, 7.5.8, 7.5.9.1, 8.2.6; RDC ANVISA 16/2013: 3.2, 5.2, 6.4; MHLW MO169: 6, 40, 47, 48, 58, 59; 21 CFR 820.120, 820.184]

MDSAP Audit Approach

Task 17

- Additional country-specific requirements: Brazil (ANVISA) and the United States (FDA)
- Assessing conformity:
  - Verify that each batch of devices was manufactured in accordance with product and production specifications
  - Confirm that the nonconformities were handled appropriately

Detailed information on how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 6: Production and Service Controls, under Task 17

Task 18

18. **If the medical device organization manufactures active or nonactive implantable medical devices, life-supporting or life-sustaining devices, confirm the manufacturer maintains traceability records of all components, materials, and work environment conditions (if these could cause the medical device to not satisfy its specified requirements) in addition to records of the identity of personnel performing any inspection or testing of these devices. Confirm that the organization requires that agents or distributors of these devices maintain distribution records and makes them available for inspection. Verify that the organization records the name and address of shipping consignees for these devices.**

Clause and Regulation: [ISO 13485:2016: 4.2.1, 7.5.9.2, 8.2.6; MHLW MO169: 6, 49, 59; 21 CFR 820.65]

MDSAP Audit Approach

Task 18

- Additional country-specific requirements: Canada (HC), United States (FDA)
- Assessing conformity:
  - Confirm that the organization has the necessary systems in place to provide for tracking each device to the end user

Detailed information on how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 6: Production and Service Controls, under Task 18

Task 19

19. Verify that product status identification is adequate to ensure that only product which has passed the required inspections and tests is dispatched, used, or installed.

Clause and Regulation: [ISO 13485:2016: 7.5.8; RDC ANVISA 16/2013: 6.1.2, 6.4; MHLW MO169: 47 (Old: 47, 50); 21 CFR 820.86]

MDSAP Audit Approach

Task 19

- Additional country-specific requirements: None

- Assessing conformity:

  Detailed information on how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 6: Production and Service Controls, under Task 19

Task 20

20. Verify that the medical device organization has implemented controls to identify, verify, protect, and safeguard customer property provided for use or incorporation into the product. Verify that the medical device organization treats patient information and confidential health information as customer property.

Clause and Regulation: [ISO 13485:2016: 7.5.10; MHLW MO169: 51]

MDSAP Audit Approach

Task 20

- Additional country-specific requirements: None

- Assessing conformity:

  Detailed information on how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 6: Production and Service Controls, under Task 20

Summary

- Production processes can include:
  - internal controls
  - equipment calibration and maintenance intervals
  - environmental controls
  - personnel controls
- The purpose of auditing the production and service controls process is to verify that the manufacturer's processes are capable of ensuring that products will meet specifications

Conclusion

- This concludes part 2 of the training module for MDSAP process: Production and Service Controls

- Please continue to part 3 to complete the discussion of the audit tasks for the Production and Service Controls process, as well as the links to other processes


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